DM Medical Inc
10865 Millington Ct
Cincinnati, Ohio 45242
Ph 800.884.6414
Fax 513.936.6555

MAY 0 3 2002

DM Medical Inc

510(k) Summary K020570
Smoke Evacuation Hoses/Tubing

Manufacturer

DM Medical Inc.
10865 Millington Ct.
Cincinnati, Ohio 45242

Manufacturing Location

Same

Contract Sterilizer – For Gamma Radiation Sterilization

IBA SteriGenics International
305 Enterprise Dr.
Westerville, Ohio 43081

Manufacturer Telephone/Email/Fax

Telephone 1-800-884-6414
Fax 1-513-936-6555
Email RMAYS@PREMEDCO.COM

Contact Person

Robert W. Mays

Device Trade Name

Smoke Evacuation Hoses/Tubing

Common Name

Smoke Evacuation Hoses/Tubing

Classification Name

Accessory to surgical exhaust apparatus

ProCode

FYD

Predicate Device

Smoke evacuation hoses/tubing manufactured and sold by LASE, INC. Originally submitted by LASE, INC. under 510(k) number K922555.

Description

A plastic smooth bore corrugated tubing with polyethylene adapters. Supplied in a variety of diameters and lengths. Also supplied in Sterile and Non-Sterile.

Intended Use

Intended for removing smoke and particles from the point of surgical activity during medical procedures that use an electrosurgical pencil or laser for cutting and/or cauterizing.

Physical/Technical Comparison

Both the device and the predicate are made from the same material, are of the same general size and shape, and have the same intended use. Both devices require and use the same attachments to a vacuum or suction apparatus in order to aspirate smoke from the surgical site.

Performance Summary

All smoke evacuation hoses are capable of maintaining adequate air flow to allow for adequate aspiration of smoke found at the site of surgical activity.

Biocompatibility Testing

The materials used for the manufacture of the smoke evacuation hoses have undergone biocompatibility testing and have been found to be non-irritating, non-cytotoxic, non-sensitizing.

Sterility and Shelf Life

The device is sterile processed using gamma radiation. They are considered sterile until the package has been opened or damaged.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 03 2002

Mr. Robert W. Mays
President
DM Medical Incorporated
10865 Millington Court
Cincinnati, Ohio 45242

Re: K020510
Trade/Device Name: Smoke Evacuation Hoses/Tubing
Regulation Number: 878.4810
Regulation Name: Laser Surgical Instrument
Regulatory Class: II
Product Code: FYD
Dated: February 9, 2002
Received: February 15, 2002

Dear Mr. Mays:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

#K020510

Statement of Indications for Use:

The smoke evacuation hoses are intended for the removal of smoke and particles generated from the point of surgical activity during a medical procedure that uses an electrosurgical pencil or laser for cutting and/or cauterizing. The are to be connected to a smoke evacuation unit securely on one end and the other end is to be held at the surgical site no farther than 2" from the point of lasering or cauterizing of tissue. They are a single use item, considered a bio-hazardous item after use in surgery, and must be disposed of after each case in a bio-hazardous bag (a red bag).

Olivia S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020510